

## **REMARKS**

Reconsideration of this application is requested in review of the amendments to the specification and the claims and the remarks presented herein.

The claims in the application are claims 11-21, all of the claims having been cancelled.

With respect to the use of the trademarks, it is believed that all of the trademarks have been used properly and have been capitalized and have ®. Also, there has been a brief description of goods covered by the trademark in each use. If the Examiner deems otherwise, he is requested to please clarify his position.

Claims 11-21 are rejected under 37 USC 112 second paragraph as failing to properly define the invention. The Examiner objected to the expression “rapidly covered” and as being indefinite for the use of a trademark in the claims. The Examiner also indicated that the applicant had failed to traverse the rejection of claims 11-21 under 37 USC 112 second paragraph as being indefinite.

Applicants respectfully traverse these grounds of rejection since the amended claims are believed to properly define the invention. The expression “rapidly” has been deleted from the claims and therefore it is believed to be definite. The trademark has been cancelled from Claim 13. With respect to the Examiner’s observation that applicant’s did not respond to the rejection of Claims 11-21 under 35 USC 112 second paragraph with the last response, it should be noted that in the first Office Action dated March 3, 2004, the Examiner had not examined Claims 11-21, but rather the original

claims and it is believed that the rewritten claims obviated the rejection set forth in the March 3, 2004 Office Action. If not, the Examiner is requested to clarify his position.

Claims 11-14, 16, 17, 20, and 21 were rejected under 35 USC 103 as being obvious over the '931, '394 and '736 Patents. The Examiner states that the '931 reference teaches a transdermal therapeutic system for administering a mixture of steroid sex hormones comprising two active ingredients having matrix layers arranged side by side wherein one matrix is loaded with gestagen and the other is loaded with estrogen and that the two matrixes are separated by space and care must be taken for sufficient spacing to prevent diffusion.

With respect to the '394 patent, the Examiner states that the reference teaches a transdermal therapeutic system for the administration of a mixture of steroid sex hormones comprising of two active ingredients containing matrix layers arranged side by side wherein one matrix is loaded with gestodene and the other is loaded with estrogen and that they are separated by a separate cover layer and the system as a whole is covered by a removable protective layer.

With respect to the '736 patent, the Examiner states that it teaches an active substance containing plaster for controlling the administration of active substances to the skin, wherein the plaster contains a backing layer, an active substance reservoir divided perpendicularly to the skin contact surface of the plaster and having at least one active substance, contact adhesive on the skin contact layer and a removable protective layer. The Examiner deems that this and the '931 patent do not teach the size or the space that separates the two matrixes but that the claim of size is not patentable. With respect to the

'394 patent, the Examiner states the same short comings as well as the '736 patent but that the size is not critical.

Applicant respectfully traverses these grounds of rejection since the references cited by the Examiner do not render obvious applicant's invention which is directed to a device for transdermic administration of two active ingredients comprising a compartment (A), containing an adhesive polymer matrix containing the first active ingredient and a compartment (B), containing an adhesive polymer matrixes containing the second active ingredient, with each polymer matrix being covered with an individual protective films a and a' and compartments (A) and (B) are supported on a peel off protective film at a distance of 1 to 10 mm apart. This is in no way suggested by the Prior Art cited by the Examiner because compartments (A) and (B) of applicant's invention are covered directly by a single peel off protective film. This means that when the protective film is removed, you then have two separate patches that need to be fixed on the skin and this is in no way taught by the Prior Art cited by the Examiner.

With respect to the '931 patent, this relates to a system comprising two active ingredients containing matrix layers arranged side by side wherein one matrix is loaded with one active ingredient and the other matrix is loaded with a second active ingredient. The two matrixes are separated by a space and care must be taken for sufficient spacing of the area's to prevent the fusion of the active ingredient into the other area and this is not applicant's invention. The difference in the devices can be seen in Figure 3 of the '931 patent and in Figures 4 and 6 of the '736 patent. There are always two separate compartments separated by a space but the two compartments are supported by the same adhesive matrix covering itself by the same peel off protective film. This means you'll

have one patch with two compartments in contrast to applicants' two separate compartments, which are fixed by two separate patches on the skin.

With respect to the '394 patent, this teaches a transdermal therapeutic reservoir system having 1-3 matrix layers adhering to the cover layer that contains the active ingredients which are permanently self adhering for these components and surrounded by a skin contact adhesive that optionally contains penetration enhancing agents and a removable protective layer. It does not teach applicant to contain their systems and therefore withdrawal of these grounds of rejection is requested.

Claims 11-17, 20 and 21 were rejected under 35 USC 103 as being obvious of the '230 patent which according to the Examiner teaches a transdermal fertility control system comprising both diregion transdermal delivery dosage units and a method of preparation wherein the dosage unit delivers different steroid hormones from different regions within a single dosage unit. Dosage units may have different shapes. Again the Examiner concedes that the '230 patent does not teach the size of the spacing claimed. Claims 15-17 were further rejected under 35 USC 103 as being obvious over the '931, '394 and the '736 taken into view of the '452 patent which is cited to show a composition that can be taken in the form of a patch comprising the progestomimetic compound, trimegestone, and the estrogen compound and deems it would have been obvious to use a transdermal patch comprising the two compartments to deliver the active ingredients. In addition, Claims 18 and 19 were rejected on the same theory of taking the further view of the '772 reference. Claims 18 and 19 were rejected on being obvious of the '230 taken in view of the '772. The '772 is cited to show a transdermal delivery system to deliver 17-beta-estradiol through the skin, comprising the drug in 2-ethylhexyl acrylate and vinyl

acetate copolymer matrix and the Examiner deems it would have been obvious to use such a matrix in the primary references.

Applicants respectfully traverse these grounds of rejection since the said references in no way teach applicant's invention and one skilled in the art cannot combine the primary, secondary and third references as the Examiner has done without the benefit of applicant's disclosure. The '452 patent merely teaches the specific ingredients used by the applicants and does not overcome the deficiencies of the primary and secondary references. The '772 reference only teaches a specific copolymer which does not overcome the deficiencies of the primary references and therefore withdrawal of these grounds of rejections is requested.

In view of the amendments to the claims and the above remarks, it is believed that the claims clearly point out applicant's patentable contribution and favorable reconsideration of the application is requested.

Should any extension of time or fees be necessary in order to maintain this Application in pending condition, appropriate requests are hereby made and authorization is given to debit account # 02-2275.

Respectfully submitted,  
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